

Exhibit I

From: rsekhar@torrentpharma.com [rsekhar@torrentpharma.com]
Sent: 7/26/2018 5:50:54 AM
To: parassheth@torrentpharma.com
Subject: Fw: Fw:RECALL Huahai issue- Valsartan API Manufacturer - Genotoxic Imp Notifications
Attachments: _gif; _; _; _jpeg; Torrent Pharmaceuticals Ltd_Valsartan recall_letter 10 7 2018.pdf; VAL - RECALL - 27-07-18.xlsx

have you booked your ticket to china

----- Forwarded by R Sekhar/Procurement/CRP/Torrent on 26/07/2018 11:20 AM -----

From: Pritesh Patel/IOD/CRP/Torrent
To: Tarak Bhadja/Procurement/CRP/Torrent@TorrentPharma
Cc: Amul.Agrawal@torrentpharma.de, Kaushal S Solanki/Finance/CRP/Torrent@TorrentPharma, Manish Bhansali/Finance/CRP/Torrent@TorrentPharma, R Sekhar/Procurement/CRP/Torrent@TorrentPharma, Paras Sheth/Procurement/CRP/Torrent@TorrentPharma
Date: 23/07/2018 04:43 PM
Subject: Re: Fw:RECALL Huahai issue- Valsartan API Manufacturer - Genotoxic Imp Notifications

As discussed, please find attached herewith details for claim :

- Direct costs - estimated qty available at the distributor & customer warehouse & its value for customer :Orion & Ecopharm..

Please note that details does NOT include

- Cost of transport - from Torrent site to pharmacy.
- Cost of destruction
- Cost of recall
- Quantity recalled from each Pharmacy in the territory : Will be available later after feedback from each pharmacies in the territory
- Cost of material , WIP, Finshed goods at Torrent mfg site
- Heumann / UK / Romania or any other countries wherein recall is affected.
- Claim from end user : any claim from consumer with side effect / loss of life due to error
- Cost/ damage/ Loss of reputation / claim from customer (attached email from Orion)

It is Orion's view that Torrent is liable for the costs and expenses resulting from the recall, as stipulated in Section 20 of the Agreement. Moreover, Orion is of the view that the failure by Torrent to supply Orion with conforming Products manufactured in accordance with GMP is in breach of the Agreement. Therefore, in addition to other remedies available for Orion, Orion reserves the right to claim from Torrent any costs and other damages resulting from the breach.

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Best Regards,
Pritesh



Torrent Pharmaceuticals Ltd_Valsartan recall_letter 10 7 2018.pdf



VAL - RECALL - 27-07-18.xlsx

Pritesh Patel---05/07/2018 09:49:08 AM---Parasbhai : As you may know val Huahai api - recall initiated due to supplier's notification @ genot

From: Pritesh Patel/IOD/CRP/Torrent

To: Paras Sheth/Procurement/CRP/Torrent@TorrentPharma

Cc: R Sekhar/Procurement/CRP/Torrent@TorrentPharma, Amul.Agrawal@torrentpharma.de, Kaushal S Solanki/Finance/CRP/Torrent@TorrentPharma, Manish Bhansali/Finance/CRP/Torrent@TorrentPharma

Date: 05/07/2018 09:49 AM

Subject: Fw:RECALL Huahai issue- Valsartan API Manufacturer - Genotoxic Imp Notifcations

Parasbhai : As you may know val Huahai api - recall initiated due to supplier's notification @ genotoxic impurities found in the proposed ROS.

Overall cost of recall will be incurred by Torrent; further any claim/ patient liability we might be responsible for the same.

- if the cost of recall can be claim from vendor

- details required for such claim.

Best Regards,

Pritesh

----- Forwarded by Pritesh Patel/IOD/CRP/Torrent on 05/07/2018 09:46 AM -----

From: Pritesh Patel/IOD/CRP/Torrent

To: Jayatibha Chakrabarti/Quality/Plant/Torrent@TorrentPharma

Cc: Sushil Jaiswal/Quality/Plant/Torrent@TorrentPharma, Amul.Agrawal@torrentpharma.de, Sandeep Ramchandran/IOD/CRP/Torrent@TorrentPharma, Shail Shah/IOD/CRP/Torrent@TorrentPharma

Date: 05/07/2018 09:27 AM

Subject: Fw: Valsartan API Manufacturer - Genotoxic Imp Notifcations

Recall is initiated by orion, let us know in case there is pending activity / acceptance between Torrent- Orion before execution of recall at Orion.

Best Regards,

Pritesh

----- Forwarded by Pritesh Patel/IOD/CRP/Torrent on 05/07/2018 09:26 AM -----

From: "Kass, Patrik" <Patrik.Kass@orion.fi>

To: "PriteshPatel@torrentpharma.com" <PriteshPatel@torrentpharma.com>

Cc: "Reilio, Pasi" <Pasi.Reilio@orion.fi>

Date: 05/07/2018 12:12 AM

Subject: FW: Valsartan API Manufacturer - Genotoxic Imp Notifications

Dear Pritesh,

please be informed that Orion has just started a recall of Valsartan and Valsartan/HCTZ in Finland, recall was required from patient level, see Aila's email below for more information. We will keep you updated about the situation.

Best regards,
Patrik

From: Vällilä, Aila

Sent: 4. heinäkuuta 2018 19:17

To: VijayKPatel@TorrentPharma.com

Cc: JayatibhaChakrabarti@TorrentPharma.com; MaitrayeeMukherji@torrentpharma.com;
SusanAby@torrentpharma.com; ShivajiMare@TorrentPharma.com; SandeepRamchandran@torrentpharma.com;
KrupeshPatel@TorrentPharma.com; HardikVora@TorrentPharma.com; SumitBasu@TorrentPharma.com;
KamleshNaik@torrentpharma.com; Kass, Patrik <Patrik.Kass@orion.fi>; Jukka, Jouko <Jouko.Jukka@orion.fi>; Järvelä,
Päivi <Paivi.Jarvela@orion.fi>; Aalto, Satu <satu.aalto@orion.fi>

Subject: RE: Valsartan API Manufacturer - Genotoxic Imp Notifications

Dear Vijay,

Thank you for the information.

We have just started recall in Finland. Recall was required from patient level as there are two major players in Finland having other than Zhejiang API in use which stay on the market. So there is enough medication for patients available. Recall level in Poland is not yet confirmed.

I noticed that you (we) are getting several APIs from Zhejiang Huahai sites. Could you clarify which kind of change control procedures they have in the case of change of synthesis. It seems that evaluation of synthesis route change and challenging of methods have failed in this case. We should get some understanding do we have risks with other APIs.

Kind regards,

Aila

From: VijayKPatel@TorrentPharma.com [mailto:VijayKPatel@TorrentPharma.com]

Sent: 4. heinäkuuta 2018 14:56

To: Vällilä, Aila; Jukka, Jouko; Järvelä, Päivi; Aalto, Satu

Cc: JayatibhaChakrabarti@TorrentPharma.com; MaitrayeeMukherji@torrentpharma.com; SusanAby@torrentpharma.com;
ShivajiMare@TorrentPharma.com; SandeepRamchandran@torrentpharma.com; KrupeshPatel@TorrentPharma.com;
HardikVora@TorrentPharma.com; SumitBasu@TorrentPharma.com; KamleshNaik@torrentpharma.com

Subject: Fw: Valsartan API Manufacturer - Genotoxic Imp Notifications

Dear Aila and Jouko,

Please find attached file of batch details as required by you with Torrent API batches and corresponding Huahai batch numbers.

A) Three batch numbers were already sent to Orion as per our record, which not part of your list, kindly check the status and revert us.

1.

1. BBC5C005E

2. BBC5C006D

3. BBC5C005D

4.

B) Three batch number in the list provided by you is having BBC5C005F* , BBC5C008D -1 and BBD3C004D-1 is having different suffix (highlighted in bold font) . Could you please elaborate the meaning of these suffix?

Please also revert the confirmation of receipt

Best Regards
Vijay K Patel
AGM QA -Formulation
Torrent Pharmaceutical Limited, Indrad
Phone No: (02764) 233671 (Ext: 436)

----- Forwarded by Vijay K Patel/Quality/Plant/Torrent on 04-07-2018 17:17 -----

From: "Jukka, Jouko" <Jouko.Jukka@orion.fi>
To: "Välilä, Aila" <Aila.Valila@orion.fi>, "VijayKPatel@TorrentPharma.com" <VijayKPatel@TorrentPharma.com>, "Sevéus, Mari" <Mari.Seveus@orion.fi>
Cc: "SandeepRamchandran@torrentpharma.com" <SandeepRamchandran@torrentpharma.com>, "JayatibhaChakrabarti@TorrentPharma.com" <JayatibhaChakrabarti@TorrentPharma.com>, "ShivajiMare@TorrentPharma.com" <ShivajiMare@TorrentPharma.com>, "Järvelä, Päivi" <Paivi.Jarvela@orion.fi>, "MaitrayeeMukherji@torrentpharma.com" <MaitrayeeMukherji@torrentpharma.com>, "SusanAby@torrentpharma.com" <SusanAby@torrentpharma.com>
Date: 04-07-2018 10:53
Subject: RE: Valsartan API Manufacturer - Genotoxic Imp Notifications

Dear Torrent team,

Since we have not received the filled list as was just discussed on TC, here are emails where to send the filled excel. Also please check your Outlook folder uploads/downloads that the email really gets uploaded.

Also please confirm the receipt of this email and that you have re-sent the filled list of batches.

Jouko.jukka@orion.fi
Aila.valila@orion.fi
satu.aalto@orion.fi
Paivi.jarvela@orion.fi

Best Regards,
Jouko Jukka
QA Specialist, QP
External Supply Operations
+358509662480

From: Välilä, Aila
Sent: 3. heinäkuuta 2018 17:48
To: Jukka, Jouko <Jouko.Jukka@orion.fi>; VijayKPatel@TorrentPharma.com; Sevéus, Mari <Mari.Seveus@orion.fi>
Cc: SandeepRamchandran@torrentpharma.com; JayatibhaChakrabarti@TorrentPharma.com; ShivajiMare@TorrentPharma.com; Järvelä, Päivi <Paivi.Jarvela@orion.fi>; MaitrayeeMukherji@torrentpharma.com; SusanAby@torrentpharma.com
Subject: RE: Valsartan API Manufacturer - Genotoxic Imp Notifications
Importance: High

Dear Vijay,

We need your confirmation early tomorrow morning concerning;

API batch number and CEP revision of the used batch for each released batch. You can use attached excel sheet for data recording. (Jouko has sent that earlier)

We got information from Authority that recalls are most probably requested.

Kind regards,
Aila

From: Väilä, Aila

Sent: 3. heinäkuuta 2018 11:15

To: Jukka, Jouko; VijayKPatel@TorrentPharma.com; Sevéus, Mari

Cc: SandeepRamchandran@torrentpharma.com; JayatibhaChakrabarti@TorrentPharma.com;

ShivajiMare@TorrentPharma.com; Järvelä, Päivi; MaitrayeeMukherji@torrentpharma.com; SusanAby@torrentpharma.com

Subject: RE: Valsartan API Manufacturer - Genotoxic Imp Notifications

Dear Vijay,

We had an extended review of the Zhejiang report with Drug Safety and following additional questions were received. Can you please communicate the following to Zhejiang. If there is something you need to clarify we can have a telecon. Please inform us if needed.

We sent some questions yesterday, are you able to response those today?

The daily max allowed exposures (max 10 µg daily for 1-10 year use) are calculated according to ICH M7(R1) in the report and that calculation results in level of 31,2ppm in API:

For adults with 1-10 years of exposure at 10 µg /day, the risk of cancer is at 10⁻⁵[Reference: ICH M7(R1), dated 31 March 2017]. Therefore, the limit of NDMA in Valsartan drug products can be set at 10 µg/day or 31.2 ppm for the maximum dose (10 µg/1000 ÷ 320 mg), if patients take Valsartan drug products at the maximum daily dose of 320 mg for 1-10 years.

In chapter 4.2. the following is stated as a recommendation:

If the absolute amount of NDMA in a single tablet (from 40 mg to 320 mg tablets) is below 10 µg, we recommend that drug product batches will remain on the market, because we believe the risk would be minimal according to the above risk analysis.

Is that really a correct recommendation? I believe it should be that the absolute amount remains below 10 µg per 320mg max daily dose. Therefore it should be 2,5 µg in 80 mg tablet, 50 µg in 160 mg tablet and 10 µg in 320 tablet?

However "10 µg/day per 320 mg" equals "31,2ppm in API" and that means that only API batches where NDMA is below 31ppm fulfill this requirement. Based on the data the API from West zone (3,4 - 27,7ppm) would be the only one on that level (table 6).

Is the API for Orion products from West zone? Is the NDMA level in API used for Orion batches exceeding 31ppm?

Kind regards,
Aila

From: Jukka, Jouko

Sent: 2. heinäkuuta 2018 13:53

To: Väilä, Aila; VijayKPatel@TorrentPharma.com; Sevéus, Mari

Cc: SandeepRamchandran@torrentpharma.com; JayatibhaChakrabarti@TorrentPharma.com;

ShivajiMare@TorrentPharma.com; Järvelä, Päivi; MaitrayeeMukherji@torrentpharma.com; SusanAby@torrentpharma.com

Subject: RE: Valsartan API Manufacturer - Genotoxic Imp Notifications

Dear Vijay,

In addition, could you please fill the attached excel sheet with API batch number and CEP revision of the used batch for each released batch. We have already highlighted the batches you have mentioned in the trailing mail. If you have any questions, please do not hesitate to ask.

Please send us the batch numbers where the new API synthesis process has been used.:

TPL Indrad Response: Product and batch number for orion is mentioned as below,

Valsartan/Hydro Orion80mg/12.5mg 7X14T	BCB8C001D
Valsartan/Hydro Orion160mg/25mg 7X14T	BCB9C002D
Valsartan Orion 320mg 7X14T	BEG7D001D
Valsartan Orion 320mg 7X14T	BEG7D002D

Best Regards,
Jouko Jukka
QA Specialist, QP
External Supply Operations
+358509662480
Jouko.Jukka@orion.fi
Orion Corporation
Orionintie 1A
PO box 65
02101 Espoo, Finland



{Kuvaobjekti}

From: Väilä, Aila

Sent: 2. heinäkuuta 2018 13:12

To: VijayKPatel@TorrentPharma.com; Sevéus, Mari <Mari.Seveus@orion.fi>

Cc: SandeepRamchandran@torrentpharma.com; JayatibhaChakrabarti@TorrentPharma.com; ShivajiMare@TorrentPharma.com; Järvelä, Päivi <Paivi.Jarvela@orion.fi>; MaitrayeeMukherji@torrentpharma.com; SusanAby@torrentpharma.com; Jukka, Jouko <Jouko.Jukka@orion.fi>

Subject: RE: Valsartan API Manufacturer - Genotoxic Imp Notifcations

Dear Vijay,

Thank you very much for the response.

Concerning API batches used in Orion products (below mentioned batches) do you already know what is the content of NDMA (N-nitrosodimethylamine) in related API batches?

Question 3) We have submitted CEP variation, so there is no need to provide this documentation package for us. It was mistake in our end that we were not able to detect that from file.

Kind regards,
Aila

From: VijayKPatel@TorrentPharma.com [<mailto:VijayKPatel@TorrentPharma.com>]

Sent: 2. heinäkuuta 2018 9:26

To: Väilä, Aila; Sevéus, Mari

Cc: SandeepRamchandran@torrentpharma.com; JayatibhaChakrabarti@TorrentPharma.com;

ShivajiMare@TorrentPharma.com; Järvelä, Päivi; MaitrayeeMukherji@torrentpharma.com; SusanAby@torrentpharma.com

Subject: Fw: Valsartan API Manufacturer - Genotoxic Imp Notifications

Dear Aila,

Please find attached our response in blue font.

1) Please send us the batch numbers where the new API synthesis process has been used.:

TPL Indrad Response: Product and batch number for Orion is mentioned as below,

Valsartan/Hydro Orion80mg/12.5mg 7X14T	BCB8C001D
Valsartan/Hydro Orion160mg/25mg 7X14T	BCB9C002D
Valsartan Orion 320mg 7X14T	BEG7D001D
Valsartan Orion 320mg 7X14T	BEG7D002D

2) What is the difference in the new API process compared to the old one (D5191 vs. C5069)?

TPL Indrad Response: Detailed investigation report of Huahai is attached herewith.

3) You mentioned that you have submitted a variation related to this API process change, however we have not received any variation package or CRF related to changes in API process/CEP, please comment and please provide the package content asap

TPL Indrad Response: We will provide you the package once received from TPL RA.

We would like to discuss the way forward in this regard via teleconference today with you , Please share your dialing details and time for the same.

Best Regards

Vijay K Patel

AGM QA -Formulation

Torrent Pharmaceutical Limited, Indrad

Phone No: (02764) 233671 (Ext: 436)

----- Forwarded by Vijay K Patel/Quality/Plant/Torrent on 02-07-2018 09:39 -----

From: "Väilä,Aila" <Aila.Valila@orion.fi>

To: "Sevéus,Mari" <Mari.Seveus@orion.fi>, "VijayKPatel@TorrentPharma.com" <VijayKPatel@TorrentPharma.com>, "Järvelä,Päivi" <Paivi.Jarvela@orion.fi>

Cc: "SandeepRamchandran@torrentpharma.com" <SandeepRamchandran@torrentpharma.com>, "JayatibhaChakrabarti@TorrentPharma.com" <JayatibhaChakrabarti@TorrentPharma.com>, "ShivajiMare@TorrentPharma.com" <ShivajiMare@TorrentPharma.com>

Date: 02-07-2018 01:35

Subject: RE: Valsartan API Manufacturer - Genotoxic Imp Notifications

Dear All,

Could you provide the responses tomorrow morning. We will need responses in communication with Authorities.

Kind regards,
Aila

Aila Väilä
QA Director, Qualified Person, QA External Supply Operations
Orion Corporation
Orionintie 1, P.O.Box 65, FI-02101 Espoo, Finland
Mobile +358 50 966 3978 Fax. +358 10 426 3254
aila.valila@orion.fi

From: Sevéus, Mari
Sent: 28. kesäkuuta 2018 13:59
To: VijayKPatel@TorrentPharma.com; Väilä, Aila; Järvelä, Päivi
Cc: SandeepRamchandran@torrentpharma.com; JayatibhaChakrabarti@TorrentPharma.com;
ShivajiMare@TorrentPharma.com
Subject: RE: Valsartan API Manufacturer - Genotoxic Imp Notifications

Dear Torrent team,

Thank you for the telecon.

- 1) Please send us the batch numbers where the new API synthesis process has been used.
- 2) What is the difference in the new API process compared to the old one (D5191 vs. C5069)?
- 3) You mentioned that you have submitted a variation related to this API process change, however we have not received any variation package or CRF related to changes in API process/CEP, please comment and please provide the package content asap

Best regards,

Mari Sevéus
QA Specialist, QP
QA External Supply Operations
Orion Corporation
Orionintie 1, P.O.Box 65, FI-02101 Espoo, Finland
Mobile +358 50 966 3340
Mari.Seveus@orion.fi

From: VijayKPatel@TorrentPharma.com [<mailto:VijayKPatel@TorrentPharma.com>]
Sent: 28. kesäkuuta 2018 13:45
To: Väilä, Aila; Sevéus, Mari; Järvelä, Päivi
Cc: SandeepRamchandran@torrentpharma.com; JayatibhaChakrabarti@TorrentPharma.com;
ShivajiMare@TorrentPharma.com
Subject: Valsartan API Manufacturer - Genotoxic Imp Notifications

Dear All,

Please find attached files of notifications received from Valsartan API Manufacturer for your perusal.

Best Regards
Vijay K Patel
AGM QA -Formulation
Torrent Pharmaceutical Limited, Indrad
Phone No: (02764) 233671 (Ext: 436)

----- Forwarded by Jayatibha Chakrabarti/Quality/Plant/Torrent on 27/06/2018 09:29 -----

From: Tarak Bhadja/Procurement/CRP/Torrent
To: Anshu Rathore/Quality/TRC/Torrent@TorrentPharma, Chetan Vekaria/Quality/TRC/Torrent@TorrentPharma, Sumit Basu/Quality/Plant/Torrent@TorrentPharma, Amaresh Singh/Quality/Dahej/Torrent@TORRENTPHARMA
Cc: Susan Aby/Quality/TRC/Torrent@TorrentPharma, Dhruvit Shah/Procurement/CRP/Torrent@TorrentPharma, Niles Trivedi/Quality/TRC/Torrent@TorrentPharma, Kishorkumar Koshe/Quality/Dahej/Torrent@TORRENTPHARMA, Jayatibha Chakrabarti/Quality/Plant/Torrent@TorrentPharma, Paras Sheth/Procurement/CRP/Torrent@TorrentPharma, Upendra Shah/Quality/TRC/Torrent@TORRENTPHARMA
Date: 26/06/2018 15:09
Subject: Fw: Notification

Further update from Huahai,

=====

Regarding the Notification on Valsartan API we sent you earlier, please kindly be advised that the material out of Old Process, with the Code No. C5069, that we supplied to Torrent up until now, has NO Genotoxic impurity potential. The issue is exclusively related to the New/Existing Process, with the Code No.D5191 for which the investigational study is being conducted. Please see attached the interim update by our Quality Unit.

=====

Best Regards,

Tarak Bhadja

----- Forwarded by Tarak Bhadja/Procurement/CRP/Torrent on 20-06-2018 19:01 -----

From: "zoe xu" <zoexu@huahaipharm.com>
To: TarakBhadja <TarakBhadja@torrentpharma.com>
Cc: PrajyotKulkarni <PrajyotKulkarni@torrentpharma.com>, DhruvitShah <DhruvitShah@torrentpharma.com>, sunnyliu <sunnyliu@huahaipharm.com>, super <super@huahaipharm.com>, uma <uma@huahaipharm.com>, Akhilesh <akhilesh@huahaipharm.com>, christinahu <christinahu@huahaipharm.com>
Date: 20-06-2018 19:00
Subject: RE: Notification

Dear Tarak,

Please kindly be informed of the notice as attached from our QA concerning product Valsartan API, and forward the same internally as appropriate.

Thanks for your attention and please confirm the receipt by return.

Best Regards
zoe xu